DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 Eighth Street, N.E.
Atlanta, Georgia 30309

November 3, 1999

VIA FEDERAL EXPRESS

Cheney Meiere, M.D.
Medical Director
Radiology Department
Wilson Medical Center
701 Cashua Ferry Road
P.O. Box 1859
Darlington, SC 29532

Inspection ID: 1470410009

WARNING LETTER

Dear Dr. Meiere:

Your facility was inspected on 10/22/99 by a representative of the South Carolina Department of Health and Environmental Control (DHEC), Radiological Health Branch, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

> Processor QC records were missing 10 consecutive days for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Darkroom.
>
> Processor QC records were missing 10 out of 10 days of operation in month 9/1999. Processor QC records missing 100%, for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Darkroom.
>
> Phantom QC records were missing for 7 weeks for unit 2, General Electric Co. (GE Medical Systems), 800T, room MAMMO.

The specific deficiencies noted above appeared under the Level 1 reading on your MQSA facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report

provided to you at the close of the inspection. The Level 2 noncompliance items are:

There is no written procedure for infection control.

Corrective action for a failing image score (before further exams) was not documented for unit 2, General Electric Co. (GE Medical Systems), 800T, room MAMMO.

For the 7 missing weeks, phantom images were performed, but not evaluated or plotted. On several occasions in 1999, the density difference of the phantom images fell outside the action limits, and no corrective action was performed.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, intitate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records. **(Note: Patient names or identification should be deleted from any copies submitted.)**

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed.

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Please send the original copy of your response to:

U.S. Food and Drug Administration
Compliance Branch
60 8th St., NE
Atlanta, GA 30309

With a copy to:

South Carolina DHEC
Radiological Health Branch
2600 Bull Street
Columbia, SC 29201

and

Thomas Clarida
U.S. Food and Drug Administration
5701 Executive Center Drive, Suite 104
Charlotte, NC 28212

(NOTE: If phantom image is required for corrective action, please submit original to SC DHEC, Radiological Health Branch.)

You may choose to address both FDA and state requirements in your response. If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas Clarida at 704-344-6116.

Sincerely yours,

Ballard H. Graham, Director
Atlanta District